

SPL Process Meeting Meeting Minutes February 26, 2014

Chair of today's meeting: Mary Beth Wilusz

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

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Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

1. Revision Dates: I would like to understand the interpretation of (the guidance below) by peers in industry and how others implement this guidance as it pertains to revision dates (in labeling). My question relates to the revision date for patient labeling and the Medication Guide. When are these dates revised by the Company? Only upon FDA approval? Should they be updated to match the revision date of the USPI if they are attached in packaging?

Meeting Discussion:

FDA guidance dated February 2013 -- "Labeling for Human Prescription Drug and Biological Products -- Implementing the PLR Content and Format Requirements" states:

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm075082.pdf>

"At the end of Highlights, the date of the most recent revision of the labeling must be presented (§ 201.57(a)(15)). The preferred format is Revised: Month Year or Revised: Month/Year in bold type (i.e., Revised: Apr 2011 or Revised: 4/2011). In PLR format, this statement replaces the revision date that appears at the end of labeling in the old format (§ 201.56(e)(5)). A new approval or changes to the approved labeling will trigger a new revision date. FDA-approved patient labeling or Medication Guides can have revision dates that differ from the revision date at the end of Highlights, if appropriate."

Does this guidance allow the Company flexibility to change the date for patient labeling or a Med Guide? It states "nonbinding recommendations". Or is it only appropriate to change the revision date of patient labeling or Medication Guide upon FDA approval of these two labeling doc types?

As FDA allows minor changes to the USPI via an annual reportable change, can minor changes to patient labeling or a Med Guide be made as annual reportable, thereby impacting the revision date?

- Regs say need to submit all Medguides for approval
 - o only annual reportable changes for a Medguide could be manufacturing type changes
 - o However, some divisions want to see all changes to the Medguide.
- Medguides and PPIs are not part of the PI Content of labeling. Therefore each document should have its own revision date, based on the approval of each document.
 - o Date on the PI doesn't change when the Medguide is approved.
 - o Medguide date is the date of approval of the Medguide itself.
 - o PI is the approval date of the PI.
 - o Date of the Medguide doesn't change based on any updates to the PI.
- If the document is printed, then there may be a different revision date for the overall piece, but the dates for the PI and Medguide should be maintained.

What happens when FDA approves a CBE-0? Has anyone had experience with FDA goes in and changes the approval date when they approved the CBE0—after the company has proceeded with printing it.

- See the reference above. The CBE should have the date of FDA receipt.
 - o One company had experience challenging FDA (citing this reg) when they tried to change it upon approval.
 - o Several companies have gone back and told FDA that the text is identical to submitted and the version has been printed and is in use.

2. Kathy Lins: Annual reportable updates to SPL documents.

- Does anyone know if there is anything in a SPL Guidance that talks about when to submit annual reportable SPL updates?
- Do most companies follow the CFR that states updates should be made in June and December? Or do companies submit AR updates every time they occur? Or do you wait until just before the AR is due to submit the most recent AR updates (which could be multiple updates that have occurred throughout the year)?

I would like to hear how other companies handle annual reportable updates?

Meeting Discussion:

- See minutes from the last meeting.

3. Is anyone having any issues meeting the May and September validation rule changes? The requestor is having concerns with his vendor – ie implementing in September.

Meeting Discussion:

- Companies on the call are not having any vendor issues.

4. NDC codes and sample packaging: Do you need to assign NDC codes to samples and drug list them?

Meeting Discussion:

- Yes you need to drug list the NDC code for the sample
- Are people putting NDC codes on their sample packaging?
 - Some companies print it on the sample
 - Some companies assign the NDC for drug listing but do not print it on the sample.